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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,610	01/31/2006	Marco Filicori	033236-0147	1532

22428 7590 09/21/2009

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EXAMINER	
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ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
09/21/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/559,610	FILICORI, MARCO	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7,8,11-13,16-19,34,37 and 45-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7,8,11-13,16-19,34,37 and 45-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

MATTER OF RECORD

The cover sheet of the previous Office Action inadvertently indicated that the action was a Final Office Action. However, the body of the action did not indicate that the action was final and it was not processed as a final rejection in PALM or eDAN. The previous Office action was intended to be a non-final action. The examiner apologizes for any confusion. Applicant's Request for Reconsideration after Final Rejection has been entered (28 July 2009).

Status of Application, Amendments and/or Claims

The amendment and Applicant's arguments, filed 28 July 2009, have been entered in full. Claims 2-6, 9, 10, 14, 15, 20-33, 35, 36, 38-44, 48 and 49 are canceled. Claims 1, 7, 8, 11-13, 16-19, 34, 37, 45-47 are amended. Claims 1, 7, 8, 11-13, 16-19, 34, 37, 45-47 are under examination.

Withdrawn Objections And/Or Rejections

The rejection to claims 20, 36 and 48 under 35 U.S.C. 112, second paragraph, as set forth at pages 3-4 of the previous Office Action (30 January 2009), is *withdrawn* in view of the amendment (filed 28 July 2009).

The rejection to claim 44 under 35 U.S.C. 112, first paragraph, written description, new matter, as set forth at pages 4-5 of the previous Office Action (30 January 2009), is *withdrawn* in view of the amendment (filed 28 July 2009).

The rejection to claims 7 and 19 under 35 U.S.C. 112, second paragraph, as set forth at pages 5-7 of the previous Office Action (30 January 2009), is *withdrawn* in view of the amendment (filed 28 July 2009).

The rejection to claims 37, 45 and 47 under 35 U.S.C. 112, first paragraph, written description, new matter, as set forth at pages 7-9 of the previous Office Action (30 January 2009), is *withdrawn* in view of the amendment (filed 28 July 2009).

The rejection to claim 47 under 35 U.S.C. 103(a) as being unpatentable over Skrabanja et al. in view of Filicori, as set forth at pages 14-15 of the previous Office Action (30 January 2009), is *withdrawn* in view of the amendment (filed 28 July 2009).

Information Disclosure Statement

Applicant states that they have previously made of record co-pending applications 11/898,470 and11/979,265, both of which are being examined by Examiner DeBerry. Applicant requests that the Office Actions issued in the co-pending applications be considered in the context of the instant application, including the Office Actions mailed August 26, 2008, and December 22, 2008, in 11/898,470, and the Office Action mailed February 13, 2009, in 11/979,265.

In response to Applicant's request, all Office Actions and/or references which are listed on a 1449 and comply with the provisions of 37 CFR §§1.97 and 1.98 will be considered by the Examiner. The Examiner notes that the IDS submitted 22 September 2008 in the instant application only lists Office Actions from 11/898,470 and11/979,265 (3 Office Actions from application 10/452,926 and one Office Action from application

11/979,265). The Examiner cannot consider Office Actions and/or references which are not made of record (i.e. listed on a 1449). Lastly, Applicant must actually submit the copies of the Office Actions to be part of this record.

Claim Rejections-35 USC § 102(b)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 11-13, 19 remain rejected under 35 U.S.C. 102(b) as being anticipated by Filicori et al. (Fertility and Sterility, Vol. 72, No. 6, Dec. 1999). The basis for this rejection is set forth at pages 9-10 of the previous Office Action (30 January 2009).

Applicant argues that claim 1 recites injectable formulations comprising **a single composition** (emphasis added) consisting essentially of specific amounts of FSH and hCG, in a pharmaceutically acceptable carrier. Applicant argues that Filicori does not disclose the use of a single composition comprising both FSH and hCG in specific amounts as claimed. Applicant argues that in regard to claims 34 and 46, Filicori discloses the use of Metrodin (urinary FSH) and Profasi (urinary hCG), which are **separate** (emphasis added) products, provided separately, and not as a single product, as claimed. Applicant argues that the claims 34 and 46 recite recombinant, which Filicori fails to disclose.

Applicant's arguments have been fully considered and are found partly persuasive. Newly amended claims 34, 45-47 now recite "recombinant". Filicori does not teach recombinant FSH and/or recombinant hCG and the rejection has been amended to reflect that. Applicant's other arguments are not found persuasive. The instant specification teaches that injectable formulations can be supplied as a product having pharmaceutical compositions containing either FSH or hCG suitable for administration separately or together. If administered separately, administration can be sequential. The product can be supplied in any appropriate package. For example, a product can contain a number of pre-filled syringes containing either FSH, hCG, or a combination of both FSH and hCG, the syringes package in a blister package or other means to maintain sterility (paragraph 0053). Claim 1 does not recite "single vial" or "single syringe". Indeed, claim 19 which depends from claim 1 recites, "an assemblage comprising a **first vial** and a **second vial**, each of said vials containing **an injectable formulation according to claim 1**..". Further, claims 34 and 46 both recite, a product comprising "a **first pharmaceutical composition**" and "a **second pharmaceutical composition**". **None of the claims recite single vial or single syringe combinations of FSH and hCG.** The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Claims 1, 11, 13, 16 and 19 remain rejected under 35 U.S.C. 102(b) as being anticipated by Thompson et al. (Fertility and Sterility, Vol. 63, No. 2, Feb 1995). The basis for this rejection is set forth at page 10 of the previous Office Action (30 January

2009). Applicant incorporates their response to the rejection under 35 USC 102(b) as being anticipated by Filicori et al. above, in response to the instant rejection. Applicant argues that Thompson does not teach a single composition of both FSH and hCG as recited in claim 1.

Applicants arguments have been fully considered but are not found to be persuasive for the reasons discussed above in the maintained rejection under 35 U.S.C. 102(b) as being anticipated by Filicori et al. The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Claims 1, 7, 8, 11, 13, 16 and 19 remain rejected under 35 U.S.C. 102(b) as being anticipated by Menezo (WO 03/022303 A2). The basis for this rejection is set forth at page 11 of the previous Office Action (30 January 2009). Applicant incorporates their response to the rejection under 35 USC 102(b) as being anticipated by Filicori et al. and Thompson above, in response to the instant rejection. Applicant argues that Menezo does not disclose a single pharmaceutical composition of both FSH and hCG. Applicant argues that Menezo teaches that FSH and hCG are administered at different time points and would not be combined together.

Applicants arguments have been fully considered but are not found to be persuasive for the reasons discussed above in the maintained rejections under 35 U.S.C. 102(b) as being anticipated by Filicori et al. and Thompson. Further, as was stated in the previous Office Action, Menezo teaches a kit comprising doses of FSH and

hCG. The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Claim 45 remains rejected under 35 U.S.C. 102(b) as being anticipated by Skrabanja et al. (US Patent No. 5,929,028). The basis for this rejection is set forth at page 12 of the previous Office Action (30 January 2009). Applicant argues that Skrabanja et al. do not disclose a single product comprising two different pharmaceutical compositions as recited in claim 45. Applicants arguments have been fully considered but are not found to be persuasive for the reasons discussed above in the maintained rejections under 35 U.S.C. 102(b) as being anticipated by Filicori et al., Thompson and Menezo. Further, as was stated in the previous Office Action, Skrabanja et al. teach gonadotropin-containing formulations comprising FSH or hCG or mixtures thereof. Skrabanja et al. teach FSH of 2-200 ug/ml. The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Claim Rejections-35 USC § 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 17 and 18 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Menezo (WO 03/022303 A2) as applied to claims 1 and 16, and further in view of

Skrabanja et al. (US Patent 5,929,028). The basis for this rejection is set forth at pages 12-14 of the previous Office Action (30 January 2009).

Applicant argues that Menezo does not disclose or suggest an injectable formulation comprising a single pharmaceutical composition of both FSH and hCG, let alone a single composition comprising FSH and hCG in the specific amounts recited in claim 1. Applicant argues that Skrabanja only discloses broad ranges of doses of each hormone, without any guidance that would lead the skilled artisan to the recited amounts. Applicant argues that combining Menezo with Skrabanja fails to suggest the present invention. Applicant argues that although Skrabanja indicates that FSH and hCG can be provided in a single composition, Menezo provides no reason for making a single preparation comprising both FSH and hCG in the same composition. Applicant argues that the claim compositions achieve results that are unexpected in view of Menezo and Skrabanja and that the claimed compositions are specifically designed to achieve ovulation induction without ovarian hyperstimulation. Applicant argues that in contrast, Menezo is specifically directed to methods for controlled ovarian hyperstimulation. Applicant argues that the skilled artisan would not expect from Menezo (or Skrabanja) that a composition as claimed could achieve ovulation induction without ovarian hyperstimulation. Applicant cites KSR. Applicant argues that the Supreme Court in KSR confirmed the significance of unexpected results to an obvious analysis, noting that combination that does no more that yield predictable results is indicative of obviousness.

Applicant's arguments have been fully considered but are not found persuasive. The Examiner has already addressed some of Applicant's arguments. As was stated above, the instant claims do not recite "single vial combinations of FSH and hCG" or "single syringe combinations of FSH and hCG". As was stated in the previous Office Action, Menezo teaches IUs of FSH and hCG that are cited in the instant claims. As was stated in the previous Office Action, Menezo teaches kits comprising both FSH and hCG. Menezo teaches liquid forms of FSH and hCG, but not liquid forms supplied in vials or cartridges. Skrabanja et al. teach liquid forms of FSH and hCG that are supplied in vials and cartridges. Because Menezo teaches the administration of FSH and hCG via injection (i.e. liquid form) and kits comprising FSH and hCG, it would be obvious to modify the kits to comprise FSH and hCG supplied in vials or cartridges. Applicant's arguments regarding unexpected or predictable results are not found persuasive because the instant claims are drawn to a formulation, which both Menezo and Skrabanja et al. teach. The instant claims are not drawn to a method of inducing ovulation without ovarian hyperstimulation. The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d

1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 7, 8, 11-13, 16-19 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of **copending Application No. 11/898,470.** The basis for this rejection is set forth at pages 15-16 of the previous Office Action (30 January 2009). Applicant request that the rejection be held in abeyance, pending identification of otherwise allowable subject matter. The instant rejection is maintained for reasons of record.

Claims 1, 7, 8, 11 and 13 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of **copending Application No. 11/979,265.** The basis for this rejection is set forth at pages 15-16 of the previous Office Action (30 January 2009). Applicant request that the rejection be held in abeyance, pending identification of otherwise allowable subject matter. The instant rejection is maintained for reasons of record.

NEW CLAIM REJECTIONS/OBJECTIONS

Claim Rejections-35 USC § 102(e)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 34, 47 and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by Sharma et al., United States Patent Application Publication US 2003/0181361. Sharma et al. teach pharmaceutical formulations comprising therapeutic proteins and polymers (abstract and para 0001). Sharma et al. teach that due to recent advances in genetic and cell engineering technologies, proteins known to exhibit various actions *in vivo* are capable of production in large amounts for pharmaceutical applications (para 0002). Sharma et al. teach that the invention provides a method to prepare aqueous sustain-release pharmaceutical formulations of therapeutic proteins for parenteral administration (para 0011). Sharma et al. teach protein expression and purification (0034). Sharma et al. teach formulations wherein the protein is selected from the group consisting of FSH and hCG (paras 0047, 0055 and claim 13). Sharma et al. teach that the formulation will contain about 1 ug/ml to about 2000 ug/ml of protein per formulation (para 0036).

Claim Rejections-35 USC § 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sharma et al. as applied to claim 34 above, and further in view of Skrabanja et al. (reference of record; US Patent No. 5,929,028). The teachings of Sharma et al. are described above. Sharma et al. teach methods to prepare aqueous sustain-release pharmaceutical formulations of therapeutic proteins for parenteral administration comprising recombinant FSH and recombinant hCG. Sharma et al. does not teach formulations further comprising a syringe.

Skrabanja et al. teach gonadotropin-containing formulations comprising FSH or hCG or mixtures thereof (abstract; column 3, lines 15-26; column 3, lines 59-65; column 4, lines 22-30). Skrabanja et al. teach methods of admixing in an aqueous solution at least one gonadotropin (column 5, lines 62-67). Skrabanja et al. teach a device for administration comprising a cartridge containing a sterile liquid formulation according to the invention. Skrabanja et al. teach that a preferred device for administration is a pen-type injector. Skrabanja et al. state that using an injector with a suitable scale indication, the patient can simply inject each time the quantity needed. (column 6, line 56-column 7, line 25).

It would be obvious to one of skill in the art at the time the invention was made to modify the aqueous sustain-release pharmaceutical formulation of therapeutic proteins

for parenteral administration comprising recombinant FSH and recombinant hCG as taught by Sharma et al. by formulating it to further comprise an injection device (i.e. syringe) as taught by Skrabanja et al. with a reasonable expectation of success. The motivation and expected success is provided by Sharma and Skrabanja, who both teach aqueous formulations comprising recombinant FSH and recombinant hCG. Because Sharma et al. teach parenteral administration of FSH and hCG, it would be obvious to supply a device to inject the pharmaceutical.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/
Primary Examiner, Art Unit 1647
/R. M. D./
Examiner, Art Unit 1647
9/17/09